IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

MATTHEW GERBER, Plaintiff,	§ § §	
v.	§	CIVIL ACTION NO. H-03-1886
	§	
HOFFMANN-LA ROCHE INC., Defendant.	§ § § §	

MEMORANDUM AND ORDER

Pending before the Court in this products liability case is Defendant Hoffmann-La Roche's Motion for Summary Judgment [Doc. # 23] ("Defendant's Motion"). Plaintiff Matthew Gerber has filed a Response to Defendant's Motion for Summary Judgment [Doc. # 30] ("Plaintiff's Response"). Defendant has filed a Reply in Support of its Motion for Summary Judgment and an Objection to Plaintiff's Evidence [Doc. # 31].[1] Having considered the parties' submissions, all matters of record, and applicable legal authorities, the Court concludes that Defendant's Motion for Summary Judgment should be **granted**.

I. FACTUAL AND PROCEDURAL BACKGROUND

Shirley Gerber visited dermatologist Michael Coverman, M.D., in November of 1983

[1] Plaintiff has also submitted a letter dated March 15, 2005 in support of its Response to Defendant's Motion. Defendant has submitted letters dated March 15, 2005 and March17, 2005 in support of its Motion.

seeking acne treatment. He diagnosed her with "inflammatory cystic acne with much early scarring and post-inflammatory hyperpigmentation." Because she had already unsuccessfully tried other acne medications and was "very discouraged," Dr. Coverman prescribed Accutane (isotretinoin or 13-*cis* retinoic acid).[2] Accutane is regarded as a uniquely effective drug for the treatment of severe recalcitrant cystic acne.[3] Since 1982, Hoffmann-La Roche ("Roche") has marketed Accutane to dermatologists for treatment of this condition. The drug is a potent teratogen[4] capable of causing malformation in embryos. Dr. Coverman "stress[ed] [to Shirley Gerber] she must not get pregnant while on this drug." Shirley Gerber explained that she utilized an intrauterine contraceptive device ("IUD").[5]

Shirley Gerber's IUD failed, and she conceived a child while taking Accutane. Plaintiff Matthew Gerber was born in November of 1984 with numerous and severe birth defects, including scoliosis, an absence of the right kidney, an imperforate anus, clubbed feet, Spengel's deformity of the right shoulder, absent ribs on his right side, and a short, webbed neck.[6] These birth defects are permanent in nature. As a result of these defects, Mr. Gerber has had to undergo numerous examinations, treatments, and surgical procedures to

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2 *See* Defendant's Exhibit A (patient treatment records of Shirley Gerber).

3 *See* Defendant's Exhibit B at ¶ 8 (Affidavit of Mark B. Weinstein, M.D.).

4 "Teratogenicity"is defined as the "property or capability of producing fetal malformation." *See* Defendant's Motion, at 6 (citing STEDMAN'S MEDICAL DICTIONARY 1796 (27th ed. 2000)).

5 *See* Defendant's Exhibit A (patient treatment records of Shirley Gerber).

6 *See* Plaintiff's First Amended Complaint at ¶ 8.

treat his deformities, and has suffered great pain and mental anguish.[7]

Mr. Gerber brings this product liability suit against Hoffmann-La Roche for damages allegedly caused by Roche's design, manufacturing, and marketing of Accutane. He alleges that Roche failed in the version of the Accutane package insert that Shirley Gerber's physician saw[8] to adequately warn dermatologists of the dangers involved with use of Accutane in women of childbearing potential. Plaintiff specifically focuses on the absence of sufficient detail about precautions for safe use of the drug in this subset of patients. In particular, Mr. Gerber alleges that Roche failed to inform doctors in 1983 that: any method of birth control can fail; IUD's fail one to two percent of the time and are expelled from a woman's uterus in five to seven percent of patients (often without the patient's knowledge); females should demonstrate multiple negative pregnancy tests before receiving Accutane; females should be on two forms of birth control concurrent with Accutane treatment; and females should receive reproductive counseling prior to treatment.[9] Roche asserts that under the "learned intermediary" doctrine, its warning was adequate as a matter of law because it warned of the specific side effect complained of; that any inadequacy in warning was not a producing cause of Mr. Gerber's injury; and that, in any event, Plaintiff cannot recover damages for "wrongful life." On Plaintiff's other claims, Roche argues that there is no

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7 *See* Plaintiff's Response, at 1.

8 Roche issued Accutane package inserts in December 1982, February 1983, and August 1983, before Dr. Coverman prescribed Accutane to Shirley Gerber. It is not clear which version Dr. Coverman saw at the relevant time.

9 *See id.* at 13.

evidence that Accutane is defective in design, and there is no evidence that the Accutane at issue was defectively manufactured.

II. LEGAL STANDARDS FOR SUMMARY JUDGMENT

Rule 56 of the Federal Rules of Civil Procedure mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a sufficient showing of the existence of an element essential to the party's case, and on which that party will bear the burden at trial. *Baton Rouge Oil and Chem. Workers Union v. ExxonMobil Corp.,* 289 F.3d 373, 375 (5th Cir. 2002) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986)).

In deciding a motion for summary judgment, the Court must determine whether "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." FED. R. CIV. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986); *Calbillo v. Cavender Oldsmobile, Inc.*, 288 F.3d 721, 725 (5th Cir. 2002). An issue is material if its resolution could affect the outcome of the action. *Terrebonne Parish Sch. Bd. v. Columbia Gulf Transmission Co.,* 290 F.3d 303, 310 (5th Cir. 2002) (citing *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 248 (1986)). In deciding whether a fact issue has been created, the facts and the inferences to be drawn from them must be reviewed in the light most favorable to the nonmoving party. *Hotard v. State Farm Fire & Cas. Co.,* 286 F.3d 814, 817 (5th Cir. 2002). However, factual controversies are resolved in favor of the nonmovant "only when there is an actual

controversy – that is, when both parties have submitted evidence of contradictory facts." *Olabisiomotosho v. City of Houston,* 185 F.3d 521, 525 (5th Cir. 1999).

The party moving for summary judgment has the initial burden of demonstrating the absence of a material fact issue with respect to those issues on which the movant bears the burden of proof at trial. *Smith v. Brenoettsy*, 158 F.3d 908, 911 (5th Cir. 1998). The movant meets this initial burden by showing that the "evidence in the record would not permit the nonmovant to carry its burden of proof at trial." *Id.* If the movant meets this burden, the nonmovant must go beyond the pleadings and designate specific facts showing that there is a genuine issue for trial. *Littlefield v. Forney Indep. Sch. Dist.*, 268 F.3d 275, 282 (5th Cir. 2001) (quoting *Tubacex, Inc. v. M/V Risan*, 45 F.3d 951, 954 (5th Cir. 1998)). A dispute over a material fact is genuine if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. *Id.* (quoting *Smith v. Brenoettsky*, 158 F.3d 908, 911 (5th Cir. 1998)); *see also Quorum Health Resources, L.L.C. v. Maverick County Hosp. District*, 308 F.3d 451, 458 (5th Cir. 2002).

The nonmovant's burden is not met by mere reliance on the allegations or denials in the nonmovant's pleadings. *See Morris v. Covan Worldwide Moving, Inc.,* 144 F.3d 377, 380 (5th Cir. 1998); *Diamond Offshore Co. v. A&B Builders, Inc.*, 302 F.3d 531, 545 n.13 (5th Cir. 2002) (noting that "unsworn pleadings do not constitute proper summary judgment evidence," quoting *Johnston v. City of Houston*, 14 F.3d 1056, 1060 (5th Cir. 1994)). Likewise, "unsubstantiated or conclusory assertions that a fact issue exists" do not meet this burden. *Id.* Instead, the nonmoving party must present specific facts which show "the

existence of a 'genuine' issue concerning every essential component of its case." *Id.* In the absence of any proof, the court will not assume that the nonmovant could or would prove the necessary facts. *McCallum Highlands, Ltd. v. Washington Capital Dus, Inc.*, 66 F.3d 89, 92 (5th Cir. 1995), *revised on other grounds upon denial of reh'g*, 70 F.3d 26 (5th Cir. 1995); *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir. 1994) (citing *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 888 (1990)).

III. ANALYSIS

A. Strict Products Liability

In Texas, strict product liability claims are generally analyzed under § 402A of the Restatement (Second) of Torts, which states in pertinent part:

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm caused to the ultimate user, consumer, or to his progeny, if
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> (a) the seller is engaged in the business of selling such a product;
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> (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

RESTATEMENT (SECOND) OF TORTS § 402A; *Uniroyal Goodrich Tire Co. v. Martinez*, 977 S.W.2d 328, 334-35 (Tex. 1998); *Brumley v. Pfizer, Inc.,* 149 F. Supp. 2d 305, 309 (S.D. Tex. 2001) (Jack, J.). In order to recover under the theory of strict liability a Plaintiff must establish (1) the defective and unreasonably dangerous condition of the defendant's product; and (2) a causal connection between such condition and the plaintiff's injuries or damages. *Lucas v. Texas Indus., Inc.*, 696 S.W.2d 372, 377 (Tex. 1984); *Brumley,* 149 F. Supp. 2d at

309. More specifically, in order to prove a claim of strict liability, the plaintiff must demonstrate that a defect in the defendant's product was the "producing cause" of his or her injuries. *See, e.g., Dico Tire, Inc. v. Cisneros*, 953 S.W.2d 776, 783 (Tex. App. – Corpus Christi 1997, writ denied).[10] A producing cause is "an efficient, exciting, contributing cause which, in a natural sequence, produced the injuries complained of." *Id.* A product may be defective if it is (1) unreasonably dangerous because adequate warnings or instructions were not provided; (2) unreasonably dangerous as designed; or (3) unreasonably dangerous as marketed. *See Caterpillar v. Shears,* 911 S.W.2d 379, 382 (Tex. 1995); *Joseph E. Seagram & Sons, Inc. v. McGuire,* 814 S.W.2d 385, 387 (Tex. 1991); *see also McLennan v. American Eurocopter Corp.,* 245 F.3d 403, 426 (5th Cir. 2001).

1. Marketing Claim – Duty to Warn

a. Applicable Legal Standard on Marketing Claims

Mr. Gerber's primary claim in strict liability is that Roche's "woefully inadequate" warnings were the producing cause of his injuries. "A marketing defect occurs when a defendant knows or should know of a potential risk of harm presented by the product but markets it without adequately warning of the danger or providing instructions for safe use." *USX v. Salinas*, 818 S.W.2d 473, 482 (Tex. App.– San Antonio 1991, writ denied) (citing *Bristol-Myers Co. v. Gonzales,* 561 S.W.2d 801, 804 (Tex.1978); *Crocker v. Winthrop*

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[10] Causation is required in all products liability cases, regardless of the theory asserted. *See, e.g., Sims v. Washex Machinery Corp.*, 932 S.W.2d 559, 562 (Houston [1st Dist.] 1995, no writ) (finding that in a failure to warn products liability claim, "the failure to warn and/or instruct must constitute a causative nexus in the product user's injury").

Laboratories, 514 S.W.2d 429, 433 (Tex.1974); and E. CARSTARPHEN, *Product Defects,* 2 TEXAS TORTS AND REMEDIES § 41.01[2] (J. Edgar & J. Sales eds. 1991)); *see also McLennan,* 245 F.3d at 427 (product is unreasonably dangerous if manufacturer fails to warn of a foreseeable risk arising from the use of the product, and lack of adequate warnings or instructions renders otherwise adequate product unreasonably dangerous); *Brumley,* 149 F. Supp. 2d at 309 (same). "It is a fundamental principle of the law of product liability in this Circuit that a manufacturer has a responsibility to instruct consumers as to the safe use of its product and to warn consumers of dangers associated with its product of which the seller either knows or should know at the time the product is sold." *Palvides v. Galveston Yacht Basin, Inc.,* 727 F.2d 330, 338 (5th Cir. 1984).

"A marketing defect cause of action consists of five elements: 1) a risk of harm that is inherent in the product or that may arise from the intended or reasonably anticipated use of the product must exist; 2) the product supplier must actually know or reasonably foresee the risk of harm at the time the product is marketed; 3) the product must possess a marketing defect; 4) the absence of the warning and/or instructions must render the product unreasonably dangerous to the ultimate user or consumer of the product; and 5) the failure to warn and/or instruct must constitute a causative nexus in the product user's injury." *Salinas,* 818 S.W.2d at 482-83 (citing SALES, *The Duty to Warn and Instruct for Safe Use in Strict Tort Liability,* 13 ST. MARY'S L.J. 521, 524 (1982)). "[I]n a marketing defect case, the injured plaintiff must raise a fact issue on the question of whether a warning or instruction should have been provided." *Id.* at 483. "[T]he plaintiff must show that the

product supplier knew or should have known of the risks at the time of marketing. *Id.* "Foreseeability is measured in terms of those dangers which are reasonable to anticipate, and the product supplier is held to the status of an expert and is assumed to possess knowledge of the latest scientific advances." *Id.* at 484.

In the prescription drug context, the "learned intermediary" doctrine applies. *See, e.g., Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir. 1999); *Reyes v. Wyeth Lab.,* 498 F.2d 1264 (5th Cir. 1974); *Brumley,* 149 F. Supp. 2d at 312; *In re Norplant Prods. Liab. Lit.,* 955 F. Supp. 700, 703 (E.D. Tex. 1997); *Alm v. Aluminum Co. of Am.,* 717 S.W.2d 588, 591-92 (Tex. 1986); *Rolen v. Burroughs Wellcome Co.,* 856 S.W.2d 607, 609-10 (Tex. App. – Waco 1993, writ denied). Under the learned intermediary doctrine in Texas, "a physician stands as an intermediary between a product manufacturer and the patient." *Porterfield*, 183 F.3d at 467 (and cases cited therein); *Brumley,* 149 F. Supp. 2d at 312 ("it is reasonable for the manufacturer to rely on the health care provider to pass on its warnings, because the provider understands the propensities and dangers involved in the use of a given drug, and as the prescriber, he stands between the drug and the consumer" (citing *Wyeth-Ayerst Lab. Co. v. Medrano,* 28 S.W.3d 87, 91 (Tex. App. – Texarkana 2000, no pet.))). "Under this doctrine, a product manufacturer is excused from warning each patient who receives the product when the manufacturer properly warns the prescribing physician of the product's dangers." *Porterfield*, 183 F.3d at 467-68 (citing *Alm*, 717 S.W.2d at 591-92). The product manufacturer may "rel[y] on the physician to pass on its warnings," although "when the warning to the intermediary is inadequate or misleading, the manufacturer remains liable for

the injuries sustained by the ultimate user." *Id.* at 468 (quoting *Alm*, 717 S.W.2d 592). Thus, a pharmaceutical supplier may fulfill its duty to warn ultimate consumers by issuing an adequate warning to an intermediary. *See Medrano,* 28 S.W.3d at 91.

The Fifth Circuit has explained, consistent with Texas courts: "In order to recover for a failure to warn under the learned intermediary doctrine, a plaintiff must show: (1) the warning was defective; and (2) the failure to warn was a producing cause of the plaintiff's condition or injury. . . . If the physician was aware of the possible risks involved in the use of the product but decided to use it anyway, the adequacy of the warning is not a producing cause of the injury." *Porterfield*, 183 F.3d at 468 (citations omitted); *Medrano,* 28 S.W.3d at 95 ("In a failure to warn case that is governed by the learned intermediary doctrine, even if we assume that the plaintiff can prove that the given warnings were inadequate, the plaintiff still must prove causation.").

Generally, under Texas law, the adequacy of a warning is a question of fact to be determined by the jury. *Brumley,* 149 F. Supp. 2d at 309; *Williams v. Upjohn Co.,* 153 F.R.D. 110, 114 (S.D. Tex. 1994); *Alm,* 717 S.W.2d at 591-92; *see also Koonce v. Quaker State Safety Prods.,* 798 F.2d 700, 716 (5th Cir. 1984) ("Whether a product supplier must provide a warning or instruction in light of the user's expertise is generally a question for the jury."). However, a claim of inadequate warning does not always present a jury issue. *See Stahl v. Novartis Pharmaceuticals Corp.*, 283 F.3d 254, 264 (5th Cir. 2002). If "a warning specifically mentions the circumstances complained of, the warning is adequate as a matter of law." *Rolen,* 856 S.W.2d at 609; *see also McNeil v. Wyeth Am. Home Prods. Corp.,* 2005

WL 544222, *4, *6 (N.D. Tex. Mar. 4, 2005) (same); *Brumley,* 149 F. Supp. 2d at 310 (same); *Medrano,* 28 S.W.3d at 95 n.6 (same). Additionally, the warning must "contain language that is adequate to ***reasonably*** inform the recipient (*i.e.*, the doctor . . .) about the nature of the danger involved." *Stahl,* 283 F.3d at 267 (emphasis added) (applying Louisiana law).

b. Adequacy of the Warnings

Roche's August 1983 package insert for Accutane, which was the one in effect in November, 1983 when Shirley Gerber was prescribed the drug, stated in relevant part:

> **CONTRAINDICATIONS: Patients who are pregnant or who intend to become pregnant while undergoing treatment must not receive Accutane. There are no adequate and well-controlled studies in pregnant women, but major fetal abnormalities related to Accutane administration have been reported, including hydrocephalus, microcephaly and abnormalities of the external ear (micropinna, small or absent external auditory canals).**
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> **Women of childbearing potential should not be given Accutane until pregnancy is excluded and an effective form of contraception is used. They should be fully counseled on the potential risk to the fetus should they become pregnant while undergoing treatment. If pregnancy does occur during treatment, the physician and patient should discuss the desirability of continuing the pregnancy.**
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> **Teratogenicity was observed in rats at a dose of isotretinoin of 150 mg/kg/day, and included microcephaly, exencephaly, spina bifida, cleft palate and abnormalities of the external ear. In rabbits a dose of 10 mg/kg/day was embryotoxic and teratogenic (primarily skeletal abnormalities) and induced abortion.**
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> * * * *
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> **WARNINGS: Because abnormalities of the human fetus have been reported, it is recommended that contraception be continued for one month**

or until a normal menstrual period has occurred following discontinuation of Accutane therapy.

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PRECAUTIONS:

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Women of childbearing potential should be instructed that they must not be pregnant when Accutane therapy is initiated, and that they should use an effective form of contraception while taking Accutane and for one month after Accutane has been stopped (See CONTRAINDICATIONS and WARNINGS.)

* * * *

Pregnancy: Category X. See "CONTRAINDICATIONS" section.[11]

Mr. Gerber alleges that Roche in this labeling failed to adequately warn dermatologists of the dangers involved with use of Accutane in women of childbearing potential, particularly with regard to precautions for safe use of the drug in this subset of patients.

To the extent that Plaintiff alleges that the Accutane package insert failed to adequately warn of the potential for birth defects, his claim is clearly invalid. The warning specifically and unambiguously mentions the circumstances of which Mr. Gerber complains, "major fetal abnormalities related to Accutane administration."[12] The label not only warns

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[11] Exhibit C to Defendant's Motion (August 1983 Accutane package insert) (emphasis in original). Category "X" indicates that a medication is contraindicated for use by pregnant women due to its teratogenicity. *See* 21 C.F.R. § 201.57(f)(6)(i)(e).

[12] Indeed, the two prior Accutane product inserts also stated that teratogenicity had been observed, and that women of childbearing potential should not be given Accutane unless an effective form of contraception is used. The December 1982 and February 1983 labels stated (continued...)

of the dangers of usage of Accutane during pregnancy, it states that use of the drug is ***contraindicated*** for patients who are pregnant, intend to become pregnant, and for women

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[12] (...continued)
in relevant part:

> CONTRAINDICATIONS: Teratogenicity was observed in rats at a dose of isotretnoin of 150 mg/kg/day. In rabbits a dose of 10 mg/kg/day was teratogenic and embryotoxic and induced abortion. There are no adequate and well-controlled studies in pregnant women.
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> Because teratogenicity has been observed in animals given isotretinoin, patients who are pregnant or intend to become pregnant while undergoing treatment should not receive Accutane. Women of childbearing potential should not be given Accutane unless an effective form of contraception is used, and they should be fully counseled on the potential risks to the fetus should they become pregnant while undergoing treatment. Should pregnancy occur during treatment, the physician and patient should discuss the desirability of continuing the pregnancy.
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> * * * *
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> WARNINGS: Although no abnormalities of the human fetus have been reported thus far, animal studies with retinoids suggest that teratogenic effects may occur. It is recommended that contraception be continued for one month or until a normal menstrual period has occurred following discontinuation of Accutane therapy.
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> PRECAUTIONS:
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> Women of childbearing potential should be instructed to use an effective form of contraception when Accutane therapy is required. (See CONTRAINDICATIONS and WARNINGS.)
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> *Pregnancy:* Category X. See "CONTRAINDICATIONS" section.

This case presents no material fact issue regarding which label Dr. Coverman saw. To the extent the 192nd Judicial District Court of Dallas County, Texas, in *Donna Buckman, et al. v. Bernard Frank Adami, et al.,* Cause No. 03-00134, has recently denied Roche's motion for summary judgment testing the adequacy of Accutane's December 1982 label, *see* Letter dated Mar. 17, 2005 from Mary R. Pawelek to Shelia Ashabranner, the Court declines to follow the *Buckman* court's lead. The weight of Texas appellate authority applied to the facts of the instant case leaves Plaintiff with no cognizable claims.

of childbearing age who are not using effective contraception. A drug's contraindications signify "those situations in which the drug should not be used because the risk of use clearly outweighs any possible benefit." 21 C.F.R. § 201.57(d). Thus this aspect of the labeling is legally significant. *See Brumley,* 149 F. Supp. 2d at 313 (noting that "[a] contraindication is more than a warning"). The evidence indicates that Dr. Coverman was in fact aware of the risk of birth defects, and advised Shirley Gerber accordingly.[13] Accordingly, Roche's warning regarding the potential for birth defects was adequate in this respect. *See Felix v. Hoffmann-La Roche Inc.,* 540 So. 2d 103, 103-05 (Fla. 1989) (referring to an earlier, less extensive label for Accutane, "it is inconceivable that reasonable persons could disagree as to the adequacy of the warnings in conveying to physicians that the prescription drug, Accutane, is dangerous to pregnant women"); *Childers v. Hoffmann-La Roche Inc.,* 540 So. 2d 102 (Fla. 1989) (affirming, on basis of *Felix,* dismissal of case against Roche based on death of child whose mother ingested Accutane during pregnancy); *see also Carter v. Hoffmann-La Roche Inc.,* 1991 U.S. Dist. Lexis 19304, *10 (S.D. Ga. Dec. 12, 1991) (unpublished opinion) (concluding "it is inconceivable that reasonable persons could disagree as to the adequacy of the warnings in conveying to physicians that the prescription drug, Accutane, is dangerous to pregnant women" (quoting *Felix, supra*)).

Plaintiff's more weighty contention is that Roche's warning is inadequate because it failed to specify the precautions necessary for safe use of the drug. A drug manufacturer,

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[13] *See* Exhibit A to Defendant's Motion (patient treatment records of Shirley Gerber, notes of 11-18-83).

just as any other manufacturer, has a duty to provide instructions regarding the safe use of its product in contemplation of dangers of which the manufacturer either knows or should know at the time of sale. *See Bristol-Myers Co. v. Gonzales,* 561 S.W.2d 801, 804 (Tex. 1978) (holding evidence adduced at trial supported jury's finding that drug's labeling should have warned doctors of certain measures necessary for safe use of drug); *Cooper v. Bowser,* 610 S.W.2d 825, 831-32 (Tex. Civ. App. 1980) (citing medical monitoring language in warning label in support of holding that warning was adequate); *see Porterfield*, 183 F.3d at 467-68 (manufacturer is excused from giving direct warnings to patients when the manufacturer "properly warns the prescribing physician of the product's dangers" (citing *Alm*, 717 S.W.2d at 591-92)). As noted above, this duty must be viewed in light of the learned intermediary doctrine, which imposes upon a physician the duty to "use his comprehensive training and experience in conjunction with his knowledge of the individual patient in determining the suitability of a medication." *Rolen,* 856 S.W.2d at 609; *see also Koonce*, 798 F.2d at 716 (where user possesses special knowledge, sophistication, or expertise, "the supplier may rely on the professional expertise of the user and tailor its warnings accordingly"). *But see Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.,* 863 F.2d 1173, 1178 (5th Cir. 1989) ("[T]he learned intermediary doctrine relates only to the issue of whom the manufacturer warned. It does not govern the adequacy of the warning."). In any event, "in order for a warning to be adequate, it must provide 'a complete disclosure of the existence and extent of the risk involved,'" and "be of an intensity justified by the magnitude of the risk." *Palvides,* 727 F.2d at 338 (quoting *Alman Bros. Farms & Feed Mill,*

Inc. v. Diamond Labs., Inc., 437 F.2d 1295, 1303 (5th Cir. 1971)).

Plaintiff argues that, given the extraordinary risk posed by Accutane, Roche should have informed doctors in 1983 that: any method of birth control can fail; IUD's fail one to two percent of the time and are expelled from a woman's uterus in five to seven percent of patients (often without the patient's knowledge); females should demonstrate multiple negative pregnancy tests before receiving Accutane; females should be on two forms of birth control concurrent with Accutane treatment; and females should receive reproductive counseling prior to treatment.[14]

In support of this argument, Mr. Gerber relies in part upon Roche's June 2002 prescribing information for Accutane, which includes four pages of "black box" warnings, the strongest type of warning required by the FDA.[15] Roche objects to this evidence on the basis of FED. R. EVID. 407, which prohibits evidence of "subsequent remedial measures" except under certain limited circumstances. Roche's expanded warning is undoubtedly a subsequent measure intended to remedy the problem of Accutane-related birth defects. Plaintiff argues that the 2002 labeling falls within Rule 407's exception regarding the feasibility of precautionary measures. Under that Rule, a party may introduce evidence of subsequent remedial measures to establish feasibility only if the issue is controverted. Roche has never argued that more extensive warnings were not feasible. Plaintiff further argues,

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[14] *See* Plaintiff's Response, at 13.

[15] *See id.* at 16-20.

without textual support or legal authority, that the 2002 labeling is admissible for other purposes, such as to demonstrate "the FDA's ongoing concern about the failure of Defendant's warnings to prevent unintended pregnancies and resulting malformed children and miscarriages." Defendant is correct in its observation that Rule 407 would effectively be repealed in all prescription drug cases if subsequent labeling were admissible to show "the FDA's ongoing concern." Roche's objection to Mr. Gerber's use of the 2002 Accutane label is sustained.[16] *See Stahl,* 283 F.3d at 270 n.10 (holding subsequent warning label not admissible under Rule 407).

Defendant contends that the additional warnings urged by Plaintiff concern facts doctors should already know as learned intermediaries. *See Brumley*, 149 F. Supp. 2d at 312 (precaution urged by plaintiff "merely alert[s] physicians to a risk of which they should already be aware"); *see also Stahl,* 283 F.3d at 268 (under Louisiana law, no duty to inform learned intermediary of obvious risks). The Court agrees. There is no dispute that in 1983 Dr. Coverman was aware of the fallibility of birth control generally, and of IUDs in particular.[17] The evidence also indicates that Shirley Gerber was aware, before she began

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[16] Roche's objection to Exhibit F to Plaintiff's Response (Letter dated Feb. 1, 1988 from Godfrey Oakley, Jr., M.D. (Director, Division of Birth Defects & Developmental Disabilities, CDC)) on the grounds of authenticity, hearsay, and relevance is sustained. Although the document is of some relevance in that it contains opinions regarding the serious dangers associated with Accutane, the letter post-dates the relevant time period by five years and thus lacks relevance or probative value concerning the issues presented for decision.

[17] *See* Exhibit A to Plaintiff's Response, at 43-44 (deposition of Michael Coverman, M.D.). Indeed, it was common knowledge that any method of birth control could fail.

Accutane treatment, that IUDs can fail.[18] The Court concludes that the combination of warnings on the August 1983 package insert that: Accutane treatment should not be prescribed for patients who are or intend to become pregnant; Accutane should not be given unless pregnancy is excluded and the patient used "effective" contraception; patients should be fully counseled on the potential risk to the fetus should the patient become pregnant while undergoing Accutane treatment; patients should consider the desirability of continuing a pregnancy should it occur while the patient is taking Accutane; abnormalities in animals were observed from the drug; "contraception [should] be continued for one month or until a normal menstrual period has occurred following discontinuation of Accutane therapy"; and "[w]omen of childbearing potential should be instructed that they must not be pregnant when Accutane therapy is initiated, and that they should use an effective form of contraception while taking Accutane and for one month after Accutane has been stopped," collectively constitute a legally adequate warning to dermatologists about the hazards of and precautions necessary for the use of the product.

c. Causation Analysis

Alternatively, because Plaintiff contends that the warning in the Accutane package insert was inadequate in failing to detail more precautions necessary for safe use of

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[18] *See* Exhibit A to Defendant's Motion (patient treatment records of Shirley Gerber, notes of 5/15/84 & 5/18/84) (recording Shirley Gerber's statement that "my only regret is that I wish I had known how unreliable the IUD was beforehand," but also stating that she had thought the IUD had a 2%-4% failure rate, and that "she knew about this possibility when she started the drug").

Accutane,[19] because there is some uncertainty as to which version of the insert Dr. Coverman saw and the earlier versions are not quite as explicit as the August 1983 insert, and because Dr. Coverman testified he might have behaved differently in limited respects had the warning been more detailed,[20] the Court will address the merits of the parties' causation arguments. *See Porterfield*, 183 F.3d at 468.

a. "Wrongful Life" Claim.– The unarticulated allegation lying beneath Mr. Gerber's claim that Roche failed to provide instructions for the "safe use" of Accutane is that Shirley Gerber would not have conceived Plaintiff but for Roche's failure to warn. The Texas Supreme Court has categorically rejected such "wrongful life" claims. *See Nelson v. Krusen*, 678 S.W.2d 918, 925 (Tex. 1984). A plaintiff cannot claim "that without [a party's] negligence the plaintiff never would have been born." *Id.* Such a claim "unavoidably involves the relative benefits of an impaired life as opposed to no life at all," a situation in which "it is impossible to rationally decide whether the plaintiff has been damaged at all," presenting "a mystery more properly left to the philosophers and theologians" than to courts. *Id.* Under the circumstances, Plaintiff can only assert an "allegation that but for the defendant's negligence [he] would have had a healthy, unimpaired life." *Id.*

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19 *See* Exhibit C to Plaintiff's Response, ¶¶ 6-7 (Affidavit of Alan S. Boyd, M.D.); Exhibit A to Plaintiff's Response, at 55-57, 59-60, 72-74, 78-81 (Deposition of Michael Coverman, M.D.).

20 *See* Exhibit A to Plaintiff's Response, at 48-49, 56-57, 65 (Deposition of Michael Coverman, M.D.).

b. Other Producing Cause Theories.– Given that Mr. Gerber cannot recover on a theory that, had Roche provided certain precautions, he would not have been born, Mr. Gerber can only argue that Shirley Gerber would not have taken Accutane in the first place if Roche's warning had been adequate. In order to prove causation under the circumstances presented in this case, Plaintiff must demonstrate that an alternative warning would have changed the physician's decision to prescribe Accutane ***or*** would have altered Shirley Gerber's decision to take the drug for her severe acne condition. *See Medrano,* 28 S.W.3d at 95; *In re Norplant,* 955 F. Supp. at 710 (citing *Wheat v. Pfizer, Inc.,* 31 F.31 340, 343 (5th Cir. 1994)).

Regarding the first issue, Dr. Coverman's decision to prescribe Accutane, Dr. Coverman continued after learning of Shirley Gerber's pregnancy to hold the opinion that "Accutane was definitely the drug of choice for her in that situation at that time as presented."[21] Knowing Shirley Gerber was pregnant, but before Mr. Gerber's birth, Dr. Coverman wrote in his treatment notes: "I would do the exact same thing again with her since I feel that I picked the most appropriate medication in that particular circumstance as she presented to me with the physical findings as well as her great subjective disability with this disease. I feel deep down that I adequately discussed with her every possibility of birth

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[21] Exhibit A to Defendant's Motion (patient treatment records of Shirley Gerber, notes of 5/15/84).

defects and the severe consequences thereof."[22] In other words, a different warning would not have changed Dr. Coverman's decision to prescribe Accutane to Mrs. Gerber at the time he did so. Plaintiff cannot show that the alleged deficiencies in the warning were a producing cause of his injuries. *See Porterfield*, 183 F.3d at 468.

There also is no evidence that a different warning would have changed Shirley Gerber's decision to take Accutane. She was fully apprised of the risks involved. The evidence indicates that Shirley Gerber was "very discouraged" with her acne and would have followed her doctor's instructions in order to receive treatment.[23] A different warning may have altered Shirley Gerber's birth control plan to better avoid pregnancy, but, as noted above, the net result of this argument is that Plaintiff would not have been born, a "wrongful life" theory which is not cognizable in Texas. Mr. Gerber attempts to raise a fact issue by arguing that Dr. Coverman testified in his deposition that the warnings contained in the relevant Accutane labeling were inadequate to inform him of the procedures necessary for safe use of Accutane.[24] Dr. Coverman testified that if Roche had specified the detailed precautions necessary for safe use of Accutane that Roche used in 2002, he would not have

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22 *Id.*

23 *See* Exhibit A to Defendant's Motion (patient records of Shirley Gerber, notes of 11/8/3, 5/15/4 & 5/18/84).

24 Exhibit A to Plaintiff's Response, at 55-57, 59-60, 72-74, 78-81 (Deposition of Michael Coverman, M.D.).

prescribed Accutane to Shirley Gerber without ensuring that she took those precautions.[25] Dr. Coverman testified that in retrospect he would have required Shirley Gerber to use two methods of contraception before taking Accutane if the manufacturer had required it at the time.[26] Regardless of Dr. Coverman's subjective opinion of how he might have done things differently had the Roche warnings been different, the warnings regarding the potential for birth defects were adequate as a matter of law. *See* Part III.A.1.b *supra*; *Brumley,* 149 F. Supp. 2d at 311-12 (holding there was no issue of fact regarding adequacy of warning, despite doctor's testimony that he would not have prescribed drug had warning been different). Even if the warnings should have been more detailed in requiring precautions for the safe use of Accutane, Mr. Gerber cannot recover on a theory that his mother would have practiced better contraception with Dr. Coverman's more attentive guidance and thereby prevented Mr. Gerber's birth if Roche's warnings had been adequate. In any event, Shirley Gerber and Dr. Coverman were fully aware that pregnancy was to be avoided. Finally, there is no dispute that Shirley Gerber was not pregnant at the time she began Accutane treatment. Defendant Roche's failure to suggest that doctors perform pregnancy tests before beginning treatment or during treatment is not a producing cause of Mr. Gerber's injury.[27]

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[25] *See id.* at 48-49, 56-57, 65.

[26] *See id.* at 48-49, 56-57. Dr. Coverman believes he is now required to follow Roche's current protocol for prescribing Accutane, which includes withholding treatment unless a woman uses two forms of birth control. *See id.* at 27-28, 31.

[27] Shirley Gerber began Accutane treatment in November 1983 and Matthew Gerber was born in November 1984. *See id.* (notes of 11/18/83); Plaintiff's First Amended Complaint, ¶ 8. (continued...)

Plaintiff has not demonstrated that the suggested alternative warning would have in fact altered Dr. Coverman's decision to prescribe the product to Shirley Gerber. Dr. Coverman's testimony about what in retrospect he might have done differently on birth control counseling or testing had there been more detailed precautions included in the Accutane package insert is not sufficient evidence to raise a fact issue that Mr. Gerber would have been born unharmed. Summary judgment is granted on Mr. Gerber's marketing defect claim.

2. Design Claim

The parties debate whether Texas law incorporates § 6(c) of the Restatement (Third) of Torts: Product Liability. It is not necessary for the Court to decide this issue because Plaintiff concedes that he has no evidence to satisfy even the less rigid § 402A of the Restatement (Second) of Torts. Comment K of the Restatement (Second) recognizes that "[t]here are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use," and that some drugs "for this very reason cannot legally be sold except to physicians, or under the prescription of a physician." Under Comment K, a prescription drug is unreasonably dangerous in design if it is not "accompanied by proper directions and warning." Texas courts further require a plaintiff asserting a design defect cause of action to demonstrate "that the defendant could

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[27] (...continued)
Finally, as the package insert recommended, Dr. Coverman urged Shirley Gerber to terminate the pregnancy, as she apparently had done on earlier occasions, and she refused, electing instead to take the risk of giving birth to a severely deformed child. *See id.* (notes of 4/18/84).

have provided a safer alternative design." *Uniroyal Goodrich Tire Co. v. Martinez,* 977 S.W.2d 328, 335 (Tex. 1988). If no safe alternative can be established, the product is not defective as a matter of law. *See id.* Plaintiff concedes that he has no evidence of a safer alternative design.[28] Summary judgment is therefore granted on Plaintiff's design defect claim.

3. Manufacturing Claim

"To recover for a manufacturing defect, the plaintiff must show a manufacturing flaw which renders the product unreasonably dangerous; that the defect existed at the time the product left the seller, and that the defect was the producing cause of the plaintiff's injuries." *Dico v. Cisneros*, 953 S.W.2d 776, 783 (Tex. App. – Corpus Christi, 1997, pet. denied). "A manufacturing defect exists when a product does not conform to the design standards and blueprints of the manufacturer and the flaw makes the product more dangerous and therefore unfit for its intended or foreseeable uses." *Id.* Plaintiff concedes that he cannot prove that the Accutane ingested by Shirley Gerber deviated in some way from the Accutane specifications. Summary judgment is granted on Mr. Gerber's manufacturing defect claim.

4. Misrepresentation Claim

Mr. Gerber also brings a misrepresentation claim pursuant to § 402B of the Restatement (Second) of Torts. Liability may be imposed under § 402B "when [a] drug company positively and specifically represents its product to be free and safe from all

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[28] *See* Plaintiff's Response, at 22.

[relevant dangers], and when the treating physician relies upon that representation, . . . [and] when the representation proves to be false and harm results." *Crocker v. Winthrop Labs.*, 514 S.W.2d 429, 433 (Tex. 1974). There is no evidence that Roche made any misrepresentations regarding safe use of Accutane in pregnant women. Summary judgment is granted on this claim.

B. Negligence (Marketing, Design, and Manufacturing)

Plaintiff also claims that Defendant was negligent in its marketing, design, and manufacture of Accutane. In a products liability claim based on negligence, the plaintiff must demonstrate that (1) the manufacturer owed a legal duty to the plaintiff; (2) the manufacturer breached that duty; (3) the plaintiff suffered an injury as a result of the breach; and (4) the defendant's actions were a proximate cause of the injury. *Mosley v. Excel Corp.*, 109 F.3d 1006, 1009 (5th Cir. 1997). The Court, even under a strict liability standard, has concluded that Roche did not fail to adequately warn of the dangers presented by Accutane, and that such a failure, if any, was not a cause of any legally cognizable injury. Mr. Gerber has conceded that it has no evidence of design or manufacturing defects.[29] Thus, Plaintiff cannot prove a breach of any duty owed by Defendant to him nor an injury caused by such a breach, and summary judgment is warranted dismissing Plaintiff's negligence claims.

C. Express and Implied Warranties

Finally, Mr. Gerber asserts causes of action for breach of express and implied warranties. There is no evidence that Roche expressly warranted that Accutane was safe for

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[29] *See* Plaintiff's Response, at 23.

use by pregnant women. To the contrary, the evidence demonstrates that Roche issued an extensive warning concerning the drug's teratogenic effect. Moreover, Plaintiff's implied warranty claim is precluded because there is no evidence Roche's product was defectively designed. *See, e.g., Sipes v. General Motors Corp.,* 946 S.W.2d 143, 158 (Tex. App. – Texarkana 1997, writ denied) ("In a products liability case, the implied warranty of merchantability is breached if the product was defective when it left the manufacturer's or seller's possession and was unfit for the ordinary purposes for which it is used because of a lack of something necessary for adequacy."); *see also Nobles v. Sofamor, S.N.C.*, 81 F. Supp. 2d 735, 741 (S.D. Tex. 1999) ("A plaintiff in an implied warranty of merchantability case must prove that the good complained of was defective at the time it left the manufacturer's or seller's possession."). Mr. Gerber's warranty claims fail as a matter of law.

IV. CONCLUSION AND ORDER

Plaintiff Matthew Gerber has no legally cognizable claims against Defendant Hoffmann-La Roche. It is therefore

ORDERED that Defendant's Motion for Summary Judgment [Doc. # 48] is **GRANTED.** It is further

ORDERED that all Plaintiff's claims are **DISMISSED**. It is further

ORDERED that Defendant's Motion to Compel [Doc. # 53] is **DENIED as moot**.

SIGNED at Houston, Texas, this **20th** day of **May, 2005.**

Nancy F. Atlas
United States District Judge